4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2012-F-0138]

Abbott Laboratories; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Abbott Laboratories has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of vitamin D_3 as a nutrient supplement in food.

FOR FURTHER INFORMATION CONTACT:

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Food and Drug Administration,

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SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2A4788) has been filed by Abbott Laboratories, 3300 Stelzer Rd., Columbus, OH 43219. The petition proposes to amend § 172.380 (21 CFR 172.380) to provide for the safe use of vitamin D_3 as a nutrient supplement in meal replacement beverages and meal replacement bars that are not

intended for special dietary use in reducing or maintaining body weight and for use in foods that are sole sources of nutrition for enteral tube feeding.

The Agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: February 29, 2012.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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